UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Civil Action No. 01-12257-PBS Judge Patti B. Saris
THIS DOCUMENT RELATES TO: ALL ACTIONS	

CONCISE STATEMENT OF UNDISPUTED MATERIAL FACTS IN SUPPORT OF SCHERING-PLOUGH CORPORATION'S AND WARRICK PHARMACEUTICALS CORPORATION'S MOTION FOR SUMMARY JUDGMENT

Pursuant to Local Rule 56.1, Defendants Schering-Plough Corporation ("Schering") and Warrick Pharmaceuticals Corporation ("Warrick") submit this concise statement of the material facts of record as to which there is no genuine issue to be tried, in support of their motion for summary judgment.

A. Average Wholesale Price

1. Average wholesale price, or "AWP," is a negotiation benchmark that has been used in the pharmaceutical industry for decades. Declaration of Harvey J. Weintraub (Mar. 10, 2006) at ¶ 11, attached as Ex. 1 ("Weintraub Decl.").[1]

2. Warrick understood AWP to be a benchmark or list price. *See* Weintraub Decl. ¶ 11; Transcript of Deposition of Harvey Weintraub (Aug. 25, 2005) at 21, the relevant portions of which are attached as Ex. 2 ("Weintraub Dep. Tr."); Transcript of Deposition of Jerome A. Sherman (July 7, 2005) at 21, the relevant portions of which are attached as Ex. 3 ("Sherman Dep. Tr.").

[1] All citations to "Ex. __" will refer to respective exhibits to the Declaration of Eric P. Christofferson Transmitting Documents Relied upon in Schering's and Warrick's Motion for Summary Judgment, filed herewith.

3. Schering understood AWP to be a benchmark or a list price. *See* Transcript of Deposition of Michael C. Walsh (July 5, 2005) at 74-75, the relevant portions of which are attached as Ex. 4 ("Walsh Dep. Tr."); Transcript of Deposition of Gary Bishop (July 27, 2005) at 30, the relevant portions of which are attached as Ex. 5 ("Bishop Dep. Tr."); Transcript of Deposition of Portia Edens (Aug. 9, 2005) at 31-32, 36, the relevant portions of which are attached as Ex. 6 ("Edens Dep. Tr.").

B. Albuterol

4. Warrick manufactures albuterol sulfate, which is at issue in this case. *In re Pharm. AWP Litig.*, MDL No. 1456 (Jan. 30, 2006) (Docket No. 2097) at 15 ("Table of Subject Drugs"); Third Amended Master Consolidated Complaint (Oct. 17, 2005) (Docket Nos. 1781-87) ¶ 136 ("TAMCC").

5. Albuterol is reimbursed under the "Durable Medical Equipment" provision of Medicare Part B. *See* 42 U.S.C. § 1395 *et. seq.*

6. The .083% and .5% albuterol solutions are primarily self-administered drugs dispensed by pharmacies for patients to use at home with the help of a nebulizer. Weintraub Decl. ¶ 14; *see also* HHS-OIG, *Update: Excessive Medicare Reimbursement for Albuterol* (OEI-03-03-00510 Jan. 2004) at i, the relevant portions of which are attached as Ex. 7.

7. Albuterol was a multi-source drug for the entire period for which plaintiffs' have calculated damages. Declaration of Sumanth Addanki, Ph.D ¶¶ 40, 43 filed herewith ("Addanki Decl.").

8. Medicare set the reimbursement rate for albuterol through four durable medical equipment regional carriers ("DMERCs"). This reimbursement rate was not published. *See* HHS-

OIG, *Medicare Reimbursement of Prescription Drugs* (OEI-03-00-00310 Jan. 2001) at i, the relevant portions of which are attached as Ex. 8.

9. Between January 1, 1994 through February 28, 2005, albuterol accounted for $182 of $269 million of allowances for inhalation drugs for Medicare Part B. HHS-OIG, *Suppliers' Acquisition Costs for Albuterol Sulfate* (OEI-03-94-00393 June 1996) at i-ii, the relevant portions of which are attached as Ex. 9.

10. Medicare allowed $178 million for albuterol sulfate 0.083% in 1996 and over $200 million in 1997. HHS-OIG, *Are Medicare Allowances for Albuterol Sulfate Reasonable?* (OEI-03-97-00292 Aug. 1998) at iii, the relevant portions of which are attached as Ex. 10.

11. In 1999, albuterol unit dose form accounted for 6.4% of total Medicare Part B drug spending and 65.8% of total Medicate Part B units. Government Accounting Office, *Medicare Payments for Covered Outpatient Drugs Exceed Providers' Cost* (GAO-01-1118 Sept. 2001) at 7, 8, the relevant portions of which are attached as Ex. 11 ("2001 GAO Report"); *see also* TAMCC ¶ 495 (citing 2001 GAO Report).

12. In 2000, Medicare paid $296 million for the unit dose form of albuterol, which represented over 43% of the $683 million Medicare paid for inhalation drugs in 2000. HHS-OIG, *Medicare Reimbursement of Albuterol* (OEI-03-00-00311 June 2000) at 1-2, the relevant portions of which are attached as Ex. 12.

13. After the patent covering the Proventil inhaler expired in December 1989, Warrick introduced a generic version of the drug, which was among the first on the market, in 1993. Addanki Decl. Exs. 4A-B; Weintraub Dep. Tr. 59, 62.

14. Albuterol products have historically been a large seller for Warrick, whereas perphenazine is much smaller. Perphenazine is a product primarily dispensed by pharmacies to be used as an anti-psychotic drug and occasionally, but rarely, administered by physicians as an anti-emetic agent. Weintraub Decl. ¶ 15. Medicare paid approximately $50,000 during the entire class period for all perphenazine prescriptions, not just those manufactured by Warrick. Addanki Decl. n.2.

C. Proventil

15. Schering manufactures Proventil, which is reimbursed under Medicare Part B. Table of Subject Drugs at 15-16; TAMCC ¶¶ 136, 487.

16. Proventil is a brand form of albuterol sulfate and is used to treat the symptoms of asthma, chronic brochitis, emphesema, and other lung diseases. TAMCC ¶ 487.

D. Generic Industry

Competition in Generic Industry

17. In the generic industry, unlike the brand industry, the competing products are identical. Weintraub Decl. ¶ 6; Addanki Decl. ¶ 31.

18. Given the presence of perfect product substitutes in the generic market, prices can change often and generally decrease over time. Addanki Decl. ¶¶ 31-32; Sherman Dep. Tr. at 65-66.

19. Pharmacies generally stock only a single manufacturer's generic product and only dispense that product. Weintraub Decl. ¶ 7.

20. Generic manufacturers compete for a pharmacy's business by offering discounts or rebates to the pharmacy, either directly or through a wholesaler. Addanki Decl. ¶¶ 31-32.

21. When prescribing generic albuterol, the prescribing physician does not typically specify the manufacturer of the albuterol to be dispensed. Weintraub Decl. ¶ 7; Sherman Dep. Tr. at 38-39.

22. When a patient presents a prescription for a generic drug, such as albuterol, the version of the product actually dispensed depends upon the pharmacy and which version it has chosen to carry. *See* Weintraub Decl. ¶¶ 7, 9; Addanki Decl. ¶¶ 31-32.

23. "Auto-substitution programs," utilized by wholesalers, involve pharmacies agreeing to take whichever manufacturers' generic a wholesaler supplies in exchange for a guarantee of the lowest possible price. Sherman Dep. Tr. at 38-39.

24. Agreements for generic products typically include a "right of first refusal," which allows a company to meet any lower price that a competitor might offer on a generic product. A right to first refusal carries with it the obligation to rebate to the customers the difference between what the customer paid for a product and the new price under the right-of-first-refusal for all products in the customer's system at the time the right is exercised. Weintraub Decl. ¶ 8.

Expression of "Spread"

25. The convention in expressing spreads - including the method used consistently by the government in many reports - is to express the spread as a percentage below AWP. Addanki Decl. ¶¶ 35-36; *see, e.g.,* 2001 GAO Report at 4 (reporting a spread of 85% from the AWP for albuterol).

26. Plaintiffs express spreads as a percentage above ASP. For example, Plaintiffs claim that Warrick touted a 529% of albuterol. *See, e.g.,* TAMCC ¶¶ 494, 497; Addanki Decl. ¶ 33.

27. In 1998, spreads as high as 85% of AWP, or approximately 550% of "ASP," were reported publicly. Addanki Decl. ¶ 36.

E. Warrick's Pricing Practices

Pricing in Competitive Market

28. The pricing of Warrick's products varies according to market conditions and can change on a daily basis. *See* Weintraub Decl. ¶ 10; Weintraub Dep. Tr. at 41; Sherman Dep. Tr. 67-66; Addanki Decl. ¶¶ 29, 31.

29. Warrick competed in the marketplace by establishing accounts and then meeting, but typically not beating, the prices offered by competitors. *See* Weintraub Decl. ¶ 10; Weintraub Dep. Tr. at 41; Sherman Dep. Tr. at 53, 67, 109-110.

30. Warrick offers or has offered discounts and rebates, including prompt pay discounts, line-based rebates, market-share rebates, and stocking allowances. Weintraub Decl. ¶ 10.

31. Upon the introduction of a generic product, Warrick and other generic manufacturers offer extended payment terms and offers to "reset" the price of all product purchased during that period at the price existing in the marketplace in a certain period after launch. *See* Sherman Dep. Tr. at 32, 35; Warrick Account Information Forms, produced at WAR004341, 16011, 16823, attached as Ex. 13 ("Account Information Forms") and discussed at Weintraub Dep. Tr. 40-41 and Sherman Dep. Tr. 28, 121.

32. Since Warrick and a wholesaler cannot know how much product will be sold under such programs at the time the product is shipped and billed, the price concessions demanded by wholesalers on the preferred position within auto-substitution programs are given by a post-sale rebate. Sherman Dep. Tr. at 32, 35; Account Information Forms.

33. It is not until after a product is sold that the amounts due under any market share rebate program can be assessed and rebates paid, typically as a credit towards future purchases. Sherman Dep. Tr. 33, 107-108; Account Information Forms.

34. Warrick also typically adjusts on-hand inventory in the event of a market price decrease. Sherman Dep. Tr. at 35; Account Information Forms.

Setting of AWP

35. When Warrick was the first to introduce a generic product, it generally set AWP at 10-20% below the equivalent brand product's AWP. Weintraub Decl. ¶ 11; *see also* Weintraub Dep. Tr. at 31; Sherman Dep. Tr. at 31, 41, 56.

36. Warrick suggests an AWP at launch and has, in almost all instances, not changed the AWP for the life of the product. Weintraub Decl. ¶¶ 11, 13; Addanki Decl. ¶ 44.

37. Warrick did not use a Medicare reimbursement rate as a basis for adjusting prices on Warrick products. Weintraub Decl. ¶ 16.

38. Warrick cannot report a single AWP that would have a uniform relationship to the many changing prices at which it sells its drugs. Weintraub Decl. ¶ 13.

39. Warrick does not typically report a list price to wholesaler (or WAC) to national pricing compedia, nor does it set or use WAC in its internal record-keeping. Weintraub Decl. ¶ 12.

40. Warrick's wholesale and retail customers were invoiced at wide range of different prices, and Warrick does not have a single list price to report as WAC. Weintraub Decl. ¶ 12.

Albuterol AWP and Market Share

41. Warrick set its AWPs for albuterol at launch at 15-20% below Proventil's AWP. Addanki Decl., Exs. 4A-B.

42. Since 1995, Warrick's AWPs for 0.083% and 0.5% solutions of albuterol have stayed the same. Addanki Decl. ¶ 44, Exs. 4A-B.

43. Warrick's AWPs for albuterol were consistently low in relation to its competitors, but Warrick has consistently achieved large market shares. Addanki Decl. ¶¶ 39, 43, Figures 2-3.

44. Following introduction of the generic version, Schering has maintained relatively high AWPs for Proventil, but its market share has been relatively low. Addanki Decl., Exs. 5A-B.

45. When Warrick's market share began declining, it did not adjust its AWPs. Addanki Decl. ¶¶ 44-45.

46. When an albuterol competitor lowered its AWP in 2002, the competitor's market share increased. Addanki Decl. ¶ 45.

F. Warrick's Marketing Practices

47. Warrick did not market the spread. Sherman Dep. Tr. at 59-60; Weintraub Dep. Tr. at 96-97.

48. At no time was Warrick aware of the Medicare reimbursement rate for albuterol, nor did it ever attempt to calculate the reimbursement rate. Weintraub Decl. ¶ 16.

49. Warrick did not provide calculations comparing its products with competitors' products based on the spread between acquisition cost and AWP. Warrick did not instruct customers to calculate the spread between the AWP and direct price and to compare that to a competitor's spread. Weintraub Dep. Tr. at 96-97.

50. Warrick competes based on product portfolio, production capacity, customer-service levels, and price. Weintraub Decl. ¶ 10; *see also* Weintraub Dep. Tr. at 41.

51. Warrick sent out price notifications listing the name of the product, its package size, its NDC, its AWP, and its "direct price," i.e., the price to the customer. Sherman Dep. Tr. at 121; Account Information Forms.

52. Warrick used a field sales force of three sales directors to sell its products. Weintraub Decl. ¶ 6.

53. Warrick used a contract telemarketing service in order to market its products to independent retailers. Weintraub Dep. Tr. at 81-83.

54. Warrick's strategy was to target a limited number of customers that supply the significant majority of the national market for its drugs. Weintraub Decl. ¶ 9.

55. AWPs were publicly available from pricing compendia. TAMCC ¶ 566.

G. Schering's Pricing Practices

56. Competitive forces in the industry drive prices down and cause the spread between AWP and ASP to increase over the life of a particular product. Addanki Decl. ¶¶ 27-30.

57. Schering AWPs are set and maintained at 20% to 25% above the manufacturer's "list price," which is referred to as "direct price" or WAC. Transcript of Deposition of Debra Kane (June 15, 2004) at 34-36, the relevant portions of which are attached as Ex. 14; Transcript of Deposition of Debra Kane (June 23, 2005) at 50-52, the relevant portions of which are attached as Ex. 15; Walsh Dep. Tr. at 74.

H. Schering's Marketing Practices

58. Schering did not market the spread. Walsh Dep. Tr. at 78-79, 105-106; Bishop Dep. Tr. at 47-49; Edens Dep. Tr. at 25-26; Transcript of Deposition of Peter Kamins (July 19, 2005) at 28-29, 97-101, the relevant portions of which are attached as Ex. 16 ("Kamins Dep. Tr.");

Transcript of Deposition of Mark David Flynn (July 29, 2005) at 26, 64-66, the relevant portions of which are attached as Ex. 17 ("Flynn Dep. Tr."); Transcript of Deposition of James Butler (Aug. 11, 2005) at 34, 77-79, the relevant portions of which are attached as Ex. 18 ("Butler Dep. Tr.").

59. Schering did not intend to market the spread by sending price notifications to customers. *See* Kamins Dep. Tr. at 40-41.

60. Schering did not instruct customers to calculate the spread in sending out price notification lists. *See* Kamins Dep. Tr. at 40-41; Transcript of Deposition of Brian Longstreet (Aug. 30, 2005) at 35-36, the relevant portions of which are attached as Ex. 19.

61. Call notes are notes that sales representatives used to memorialize their meetings and conversations with physicians in the course of selling Schering's products. *See, e.g.,* Edens Dep. Tr. at 37-38; Butler Dep. Tr. at 47-48; Bishop Dep. Tr. at 14-15.

62. Schering sales representatives testified that discussions about reimbursement with physicians were rare and were primarily limited to answering questions about the mechanics of the Medicare reimbursement process by physicians who had not participated in the Medicare program. *See, e.g.,* Edens Dep. Tr. at 69-70; Flynn Dep. Tr. at 40-44, 57-58; Butler Dep. Tr. at 60-63; Bishop Dep. Tr. at 69-72.

I. Government Policy

63. Medicare based reimbursement for multiple-source drugs and biologicals on a flat rate calculated as "the lesser of the median average wholesale price for all sources of the generic forms of the drug or biological or the lowest average wholesale price of the brand name forms of the drug or biological." 42 C.F.R. § 405.517 (now superseded); *see also* TAMCC ¶ 200; Addanki Decl. ¶ 40 n.22.

64. Since the early 1990s, Schering and Warrick have been required to report "average manufacturer's price" and "best price" for their products to the same agency that administers Medicare. *See* 42 U.S.C. § 1396r-8.

65. The regulation regarding manufacturer's "average sales price," passed pursuant to the Medicare Modernization Act of 2003, specifies numerous variables which manufacturers must consider in performing the calculation. *See* 42 C.F.R. § 414.804(a).

J. Government Reports

66. Between 1996 and 2004, government reports announced spreads as high as 89% off AWP for albuterol sulfate. As early as 1996, the government reported spreads of 65% of AWP for albuterol sulfate. Addanki Decl. ¶ 36, Exs. 3A-B.

67. In June 1996, HHS-OIG reported that "using the median of the published average wholesale prices does not reflect the actual wholesale pricing of albuterol sulfate that is occurring in the marketplace." The study found that most customers in retail or mail order pharmacies paid less for albuterol-sulfate than Medicare did. The study also found that buying groups, who negotiate prices from drug manufacturers for member pharmacies, were able to negotiate prices for albuterol sulfate that were between 56 and 70 percent lower than the Medicare reimbursement. HHS-OIG, *A Comparison of Albuterol Sulfate Prices* (OEI-03-94-00392 June 1996) at 4-7, the relevant portions of which are attached as Ex. 20.

68. In June 1996, HHS-OIG reported that "Medicare allowances for albuterol sulfate are excessive compared to suppliers' costs for the drug." Based on a study of supplier acquisition costs from January 1994 to February 1995, the report found that suppliers paid an average of $0.19 per milliliter to acquire albuterol sulfate, while Medicare was reimbursing the drug at between $0.40 and $0.43 per milliliter. The report concluded that Medicare could have saved $94 million if it had

based reimbursement on the average of supplier invoice costs. HHS-OIG, *Suppliers' Acquisition Costs for Albuterol Sulfate* (OEI-03-94-00393 June 1996) at 6, 9, the relevant portions of which are attached as Ex. 9.

69. In August 1998, HHS-OIG reported that Medicare reimbursements exceeded acquisition cost by up to 333 percent more than acquisition costs for the albuterol sulfate. This study found that Medicare allowance for albuterol sulfate in 1998 ($0.39 per ml) was between 56 to 550 percent more than the Department of Veterans Affairs paid and 20 percent more than the average Medicaid paid for the drug. HHS-OIG, *Are Medicare Allowances for Albuterol Sulfate Reasonable?* (OEI-03-97-00292 Aug. 1998) at 7-9, the relevant portions of which are attached as Ex. 10.

70. In June 2000, HHS-OIG reported that Medicare reimbursement for albuterol was almost seven times greater than the price the VA paid and almost twice Medicaid's upper limit for the drug. The report noted that a customer at a retail pharmacy would pay a median price of $0.38 per ml (or 0.25 per ml from an Internet pharmacy) whereas Medicare reimbursed $0.47 per ml. HHS-OIG, *Medicare Reimbursement of Albuterol* (OEI-03-00-00311 June 2000) at 1-2, 10-12, the relevant portions of which are attached as Ex. 12.

71. In March 2002, HHS-OIG reported that HHS-OIG has "consistently found that the published average wholesale prices currently used by Medicare to establish reimbursement amounts bear little or no resemblance to actual wholesale prices that are available to suppliers and large government purchasers." The report found that Medicare reimbursement for albuterol ($0.47 per mg) was nine times greater than the price at which the Department of Veterans Affairs paid to acquire the drug ($0.05 per mg) and six times higher than the median catalog price available to suppliers ($0.09 for median supplier invoice price and $0.11 for the median wholesale acquisition

cost reported by manufacturers). HHS-OIG, *Excessive Medicare Reimbursement for Albuterol* (OEI-03-01-00410 Mar. 2002) at 8-12, the relevant portions of which are attached as Ex. 21.

72. In January 2004, HHS-OIG reported that, in 2002, Medicare could have saved $263 million if it had reimbursed albuterol at the FUL set under Medicaid ($0.17 per mg) rather than at 95 percent of AWP. The report also found that, for 2003, Medicare reimbursement for albuterol was eight times higher than the median price available to suppliers (median price of $0.06 per mg) and nine times higher than the median price available to the VA ($0.05 per mg). HHS-OIG, *Update: Excessive Medicare Reimbursement for Albuterol* (OEI-03-03-00510 Jan. 2004) at 7-10, the relevant portions of which are attached as Ex. 7.

Schering-Plough Corporation and
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By their attorneys,

/s/ Eric P. Christofferson

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Dated: March 15, 2006

CERTIFICATE OF SERVICE

I hereby certify that on March 15, 2006, I caused a true and correct copy of the foregoing to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL 1456.

/s/ Eric P. Christofferson
Eric P. Christofferson